K042324

Summary of Safety and Effectiveness
Lyphochek Elevated Immunosuppressant Control

1.0 **Submitter**

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Contact Person

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Date of Summary Preparation

August 20, 2004

2.0 **Device Identification**

Product Trade Name:	Lyphochek Elevated Immunosuppressant Control
Common Name:	Multi-analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 864.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Lyphochek Whole Blood Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K022041

4.0 **Description of Device**

This product is prepared from human whole blood with added chemicals and preservatives. This product is provided in lyophilized form for added stability.

5.0 **Intended Use**

Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing.

6.0 **Preservatives:**

The Lyphochek Elevated Immunosuppressant Control does not contain sodium azide as a preservative. It contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic

and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Lyphochek Elevated Immunosuppressant Control claims substantial equivalence to the Lyphochek Whole Blood Control currently in commercial distribution (K022041).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Lyphochek Elevated Immunosuppressant Control (New Device)	Bio-Rad Laboratories Lyphochek Whole Blood Control (Predicate Device K022041)
Similarities		
Intended Use	Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing.	Lyphochek Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Processed Human Whole Blood Lysate	Processed Human Whole Blood Lysate
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Reconstituted Vial Claim	14 days at 2°C to 8°C	14 days at 2°C to 8°C
After Reconstituting and Freezing	After reconstituting and freezing, the product will be stable for 30 days when stored tightly capped at -10 to -20°C.	After reconstituting and freezing the control, all analytes will be stable for 30 days when stored tightly capped at -10 to -20°C.
Differences		
Levels	Bi-level (Levels 4 and 5)	Tri-level (Levels 1, 2 and 3)
Analytes	Contains the following analyte: • Cyclosporine Does not contain the following analytes: • Lead • Red Cell Folate • Tacrolimus • Sirolimus	Contains the following analytes: • Cyclosporine • Lead • Red Cell Folate • Tacrolimus • Sirolimus

8.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Lyphochek Elevated Immunosuppressant Control. Product claims and a summary of the protocols used to establish claims are as follows:

- Open vial Stability: 14 days when stored tightly capped at 2 to 8°C.
- After reconstituting and freezing: 30 days when stored tightly capped at –10 to -20°C.
- Shelf Life: Three years and three months when stored at 2 to 8 °C

Real time studies will be ongoing to support the shelf life of this product.
All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 - 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/ Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k042324
Trade/Device Name: Lyphochek Elevated Immunosuppressant Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: August 20, 2004
Received: August 27, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042324

Device Name: **Lyphochek Elevated Immunosuppressant Control**

Indications For Use: **Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing.**

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042324